MR#34767

PUBLIC COPY

August 7, 2012

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

Generic Name: [disubstituted-carbomonocyclyl-dialkyl-heteromonocyclyl]-trisubstituted-carbomonocyclyl amine

This letter is to inform you of the results of a Hershberger Assay with the above referenced R&D test substance. The test substance is an R&D substance and to the best of our knowledge not on the public inventory.

In the androgenic study, 2 groups of young adult castrated SD rats (6/group) were dosed by oral gavage with 0 or 1000 mg/kg/day of the test substance for 10 consecutive days. A separate castrated positive control group, administered 0.4 mg/kg/day of the androgen receptor agonist testosterone propionate (TP), was included to verify test system performance. In the antiandrogenic study, 2 groups of young adult castrated rats (6/group) were dosed by oral gavage with 0 or 1000 mg/kg/day of the test substance for 10 consecutive days. A separate castrated positive control group, administered 3 mg/kg/day of the androgen receptor antagonist flutamide (FT), was included to verify test system performance. In addition to the test substance or positive control treatment, all treatment groups in the antiandrogenic study also received a daily injection of 0.4 mg/kg of the reference androgen receptor agonist, TP. Body weights,clinical observations, and food consumption were recorded during the study. At necropsy, organ weights [liver, ventral prostate, seminal vesicle (plus fluids and coagulating glands), levator ani-bulbocavernosus muscle (LABC), paired Cowper's glands and the glans penis] were collected. In the both the androgenic and anti-androgenic studies, the results with the positive control chemicals were consistent with their mode-of-action, indicating the assay responded as expected. In both studies, statistically significant decreases in food consumption and body weight parameters and increases in liver weights compared to the vehicle control group were noted. In the antiandrogenic study, absolute and relative Cowper's gland weights (27% and 21% respectively) and LABC weights (20% and 14%, respectively) were statistically significantly decreased compared to the vehicle control group.

Sincerely,

Company Sanitized

Substantiating Claims of Confidentiality in Submissions to the TSCA §8(e) Office

Confidential Business Information Substantiation

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

   Yes

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

   The claimed CBI should be maintained as confidential for [ ] or until the company makes the CBI public to allow sufficient time to put in place full patent protection from competitors prior to commercialization.

3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

   The substance has been disclosed in a patent filing. The patent has published but the compound is not specifically named. It is covered in a generic claim that embraces thousands of potential analogs.

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

   Chemical identity information and regulatory data are maintained in restricted access databases. Access to the information is on a need-to-know basis in compliance with company trade secret and information security policies.

5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

   The claimed CBI has been disclosed outside the company only to those who have executed a non-disclosure agreement (NDA) covering the claimed CBI. The NDA prohibits the recipient from disclosing the claimed CBI for a period of [ ], unless it becomes otherwise publicly known before that time expires.

6. Does the information claimed as confidential appear or is it referred to in any of the following:

a. Advertising or promotional material for the chemical substance or the resulting and product; No

b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale); No

c. Professional or trade publications; or
No

d. Any other media or publications available to the public or to your competitors.
No

If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

No

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitor's access to your customers. Address each piece of information claimed CBI separately.

Disclosure of the claimed CBI reveals details of the company's R&D programs before patents and regulatory submissions are fully in place to protect company intellectual property.

9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

The substance has been disclosed in patent filings as part of a generic class of compounds. The claimed CBI is included in a patent application as part of thousands of compunds claimed. [ ].

10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market? No

a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?
The substance is not on the commercial market.

b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.

The substance is an R&D material. It is estimated that a market will be established in approximately [ ].

c. What is the substance used for and what type of product(s) does it appear in.

The substance is an R&D material and does not appear in any products.

11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?

Disclosure of the chemical identity would allow our competitors to know which substances are of specific interest to the company and therefore would accelerate their R&D work to introduce similar competitive offerings into the same markets.

12. Do you assert that disclosure of this information you are claiming CBI would reveal:

a. confidential processes used in manufacturing the substance; No

b. if a mixture, the actual portions of the substance in the mixture; No

c. information unrelated to the effects of the substance on human health or the environment? No

If your answer to any of the above questions is yes, explain how such information would be revealed.

13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.

No CAS number has been assigned. [ ].

14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.
The substance is intended for use as a pesticide but a FIFRA application has not been made to date. The substance claimed as CBI may be the future subject of FIFRA pending further R&D work to demonstrate that the substance meets all technical, regulatory, and business requirements of a new product.